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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/347,315	07/02/99	TALWAR	N RLL-1.1US

EXAMINER	
WARE, T	
ART UNIT	PAPER NUMBER
1615	3

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DATE MAILED: 01/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/347,315	Applicant(s) TALWAR ET AL.	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *02 July 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of preliminary amendment filed 7-2-99. Claims 1 and 33 have been amended and claims 47-50 have been canceled. Claims 1-46 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term viscolyzing agent is unclear, since no definition is provided as to whether the agent is meant to increase or decrease viscosity. Furthermore, it appears the term may be used contrary to applicants' intent. "-Lyzing" connotes "breaking" or "decreasing" such as in the word "hydrolyze." However, it appears applicants intend to increase viscosity with the "viscolyzing agent," since the disclosed viscolyzing agents are various gums. Clarification is requested. The examiner suggests amending the claim with "viscosity enhancing agent" to overcome this rejection, if applicants' intent is to increase viscosity.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the

explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation therapeutic drugs, and the claim also recites chemotherapeutic, antibiotic, anti-cancer, etc which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-26 and 32-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (5,292,518; hereafter '518).

'518 teaches prolonged-release drug tablet formulations comprising poly-uronic acids, gums, carbonates, crosslinked polyvinylpyrrolidone, and edible organic acids, wherein the formulations provide controlled release in the stomach and intestines (C2, L18-22; C5, L58-C6,

L7; C6, L14-17, 61-C7, L14; Examples). '518 teaches that the active compound is not critical, but that antihistamines may be incorporated into the composition. Also, it is the position of the examiner that since the mixture is blended together that the mixture of '518 is homogenous. '518 teaches the ranges or ingredients of the instant application.

6. Claims 1-6, 9-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chauhan et al (5,597,844; hereafter '844).

'844 teaches tablet compositions of cimetidine, crosslinked polyvinylpyrrolidone, bicarbonates, poly-uronic acids, hydroxypropylmethylcellulose, and gums (C2, L43-C3 L15; Examples). The compositions of '844 float on the contents of the stomach and are blended together in a dry powder mix. It is the position of the examiner, in the absence of unexpected results, that it would be obvious to one skilled in the art to substitute cimetidine with ranitidine, since both are H2-antagonists with the reasonable expected result of blocking H2-receptors in an effort to treat stomach ulceration.

7. Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (5,292,518; hereafter '518) Chauhan et al (5,597,844; hereafter '844) or vice versa.

'518 teaches prolonged-release drug tablet formulations comprising poly-uronic acids, gums, carbonates, crosslinked polyvinylpyrrolidone, and edible organic acids, wherein the formulations provide controlled release in the stomach and intestines (C2, L18-22; C5, L58-C6, L7; C6, L14-17, 61-C7, L14; Examples). '518 teaches that the active compound is not critical, but that antihistamines may be incorporated into the composition. Also, it is the position of the

examiner that since the mixture is blended together that the mixture of '518 is homogenous. '518 teaches the ranges or ingredients of the instant application.

'844 teaches tablet compositions of cimetidine, crosslinked polyvinylpyrrolidone, bicarbonates, poly-uronic acids, hydroxypropylmethylcellulose, and gums (C2, L43-C3 L15; Examples). The compositions of '844 float on the contents of the stomach and are blended together in a dry powder mix. It is the position of the examiner, in the absence of unexpected results, that it would be obvious to one skilled in the art to substitute cimetidine with ranitidine, since both are H2-antagonists with the reasonable expected result of blocking H2-receptors in an effort to treat stomach ulceration.

'518 does not teach the inclusion of hydroxypropylmethylcellulose in the drug tablet formulations. However, based upon the teachings of '844, it would be obvious to one skilled in the art to include hydroxypropylmethylcellulose in an effort to modulate the viscosity of the composition. While '518 teaches the inclusion of poly-uronic acids, it is not clear whether '518 specifically teaches that alginates are poly-uronic acids, since '518 teaches algal polysaccharides. '844, however teaches that alginate is a poly-uronic acid, and it would therefore be obvious to one skilled in the art to substitute alginate for pectin.

'844 does not teach the inclusion of edible organic acids in the drug tablet formulations. However, based upon the teachings of '518, it would be obvious to one skilled in the art to include edible organic acids in an effort to modify the flavor of the composition.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sugden et al discloses capsules comprising gums, bicarbonate gas generators, and alginate. Ahmed et al (5,728,401) discloses effervescent ranitidine formulations comprising organic acids, bicarbonate gas generators, and hydroxypropylmethycellulose. Sims et al (5,288,507) discloses ibuprofen antacid compositions. Pearman (5,188,839) teaches cimetidine compositions comprising sodium bicarbonate, alginates, and crosslinked polyvinylpyrrolidone.

9. Currently, no claim is allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on Monday through Friday from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235 or 308-1234.

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1-14-00

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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